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No. 08-705

IN THE

Supreme Court of the United States

APOTEX, INC. and APOTEX CORP.,

Petitioners,

v.

ROCHE PALO ALTO, LLC,

(formerly known as SYNTEX (U.S.A.) LLC,
and ALLERGAN, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Court of Appeals for the Federal Circuit erred in holding that the reverse doctrine of equivalents, a defense to patent infringement, which this Court has repeatedly recognized, is no longer valid.

2. Whether a court in a patent matter, in granting summary judgment under Federal Rule of Civil Procedure 56(c), makes an improper credibility determination by rejecting unrebutted scientific expert testimony proffered by the non-moving party and supported by facts recognized as the law of the case.

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE

Petitioner

Petitioner, Apotex Corp. is an affiliate of Petitioner Apotex, Inc., both privately held Canadian corporations. TorPharm, Inc. is the predecessor of Apotex, Inc. and is no longer in business. No publicly held company owns 10 percent or more of Apotex Corp.'s or Apotex, Inc.'s stock.

Respondents

Respondents are Roche Palo Alto LLC (f/k/a Syntex (U.S.A.) LLC) and Allergan, Inc. Capital Group International, Inc., a privately held corporation, owns greater than 10 percent of Allergan, Inc. Roche Palo Alto is a wholly owned subsidiary of Roche Holdings, Inc., whose parent is Roche Holding Ltd. Novartis AG, a publicly held corporation, owns greater than 10 percent of the voting shares in Roche Holding Ltd.

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PETITION FOR A WRIT OF CERTIORARI

Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Petitioner") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit was entered on July 9, 2008 and is unreported. (App. A at 1a) The order denying the Petition for Panel Rehearing and Rehearing *En Banc* was entered on September 5, 2008 and is also unreported. (App. D at 52a) The decision of the United States District Court for the Northern District of California was entered on September 11, 2007 and is reported at 526 F.Supp.2d 985 (N.D. Cal. 2007). (App. C at 22a)

JURISDICTION

The Court of Appeals entered its judgment on July 9, 2008 (App. A at 1a) and denied the Petition for Panel Rehearing and Rehearing *En Banc* on September 5, 2008. (App. D at 52a) The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) to review the Court of Appeals' decision on writ of certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

I. Supreme Court Rule 10(c):

> "Review on a writ of certiorari is not a matter of right, but of judicial discretion. A petition for a writ of certiorari will be granted only for compelling reasons. The following, although neither controlling nor fully measuring the Court's discretion, indicate the character of the reasons the Court considers:
>
> * * * *
>
> (c) a state court or a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court.

II. Federal Rule of Civil Procedure 56(c), which reads, in relevant part:

> The judgment sought should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

III. 35 U.S.C. § 112 of the Patent Act, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
>
> A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.
>
> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.
>
> A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and

then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

STATEMENT OF THE CASE

This case presents to the Court two important questions of federal law:

First, whether the Court of Appeals for the Federal Circuit erred in refusing to recognize the continued validity of the reverse doctrine of equivalents, which this Court has repeatedly held to be valid and binding. The Court of Appeals for the Federal Circuit rejected the reverse doctrine of equivalents in its opinion in this matter and has questioned the validity and continued existence of the doctrine in earlier opinions. The Court of Appeals for the Federal Circuit's holding is one in a series of similar holdings from that court regarding the reverse doctrine of equivalents that conflict with one another and with the precedent of the Supreme Court,

thereby creating great uncertainty in the litigation of patent matters.

The reverse doctrine of equivalents, enunciated and affirmed by this Court, states that "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim" the accused device does not infringe. *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 at 608-9, 70 S.Ct. 854 at 856 (1950).

The Court of Appeals for the Federal Circuit, in the present matter, affirmed the district court's grant of summary judgment of infringement against Petitioner, holding that Petitioner did not demonstrate non-infringement under the reverse doctrine of equivalents despite Petitioner's presentation of prima facie evidence to the contrary. In doing so, the Court of Appeals erred.

Second, whether the presentation of unrebutted testimony of an expert as to a material fact on behalf of a non-moving party precludes summary judgment against that non-moving party. The Court of Appeals for the Federal Circuit rendered an opinion in this matter without regard, and contrary to the testimony of Petitioner's scientific expert with respect to a material fact, the "principle" of Respondent's patent and the relation thereto of Petitioner's product. The testimony of Petitioner's expert, however, was attacked only by attorney argument and was never disputed by Respondent through contrary scientific evidence. The opinion of the district court in granting summary judgment and the Court of Appeals for the Federal

Circuit affirming that grant, therefore failed to accept Petitioner's evidence as true or to draw all inferences regarding that evidence in favor of the non-movant. To do so is incongruous with the well-established precedent of this Court and is, therefore, clear error.

REASONS FOR GRANTING THE PETITION

I. The Court of Appeals' Decision in this Matter is Contrary to and Rejects the Precedent of this Court Which Establishes and Reaffirms the Reverse Doctrine of Equivalents

a. The Reverse Doctrine of Equivalents is Sound as a General Principle of Law

Over 110 years ago, this Court established the reverse doctrine of equivalents in the patent matter *Boyden Power-Brake Co. v. Westinghouse* and proclaimed the doctrine "sound as a general principle of law," 170 U.S. 537, 569, 18 S.Ct. 707, 723 (1898). More than 50 years later the Court reaffirmed and expanded that proclamation in *Graver Tank & Mfg. Co. v. Linde Air Products Co.* holding that "[t]oday the doctrine is applied to mechanical or chemical equivalents in compositions or devices." 339 U.S. 605 at 609, 70 S.Ct. 854 at 856 (1950). This Court has demonstrated a long history of adherence to the reverse doctrine of equivalents in cases like the one at bar and has never rendered a contrary opinion. Yet, the Court of Appeals for the Federal Circuit has not followed suit, choosing not to apply this Court's precedential doctrine. The holdings of the Court of Appeals for the Federal Circuit

form a varied judicial history regarding the reverse doctrine of equivalents, precluding certainty on the existence and application of that doctrine.

b. Significant Confusion and Uncertainty Exist Due to the Varied Case Law Regarding the Reverse Doctrine of Equivalents

The holdings of the Court of Appeals for the Federal Circuit, including in the case at bar, form an inconsistent body of law regarding the continued application of the reverse doctrine of equivalents. In its own words, "[n]ot once has [the Court of Appeals for the Federal Circuit] affirmed a decision finding noninfringement based on the reverse doctrine of equivalents." *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357 at 1368 (Fed. Cir. 2002). The Court of Appeals' words suggest that it has wholly dispatched the reverse doctrine of equivalents and in the view of the Court of Appeals, "with good reason." *Id.*

According to the Court of Appeals, the enactment by Congress of 35 U.S.C. §112 after this Court's decision in *Graver Tank* may constitute a codification of the reverse doctrine of equivalents, thereby extinguishing the judicial doctrine. In *In re Donaldson Co., Inc.*, 16 F.3d 1189, 29 U.S.P.Q.2d 1845 (Fed. Cir. 1994), the Court of Appeals for the Federal Circuit wrote that "there is no legislative history suggesting that Congress's purpose in enacting [35 U.S.C. § 112] paragraph six was to codify the reverse doctrine of equivalents . . . [However,] this is not to say that this may not have been one of the *results* of enacting this paragraph." *In re Donaldson* at 1194, n. 5 (emphasis in original).

But the Court of Appeals' reasoning defies logic. It cannot be overlooked that the Court of Appeals for the Federal Circuit has itself called the argument that Congress intended §112 to codify the reverse doctrine of equivalents "imaginative reasoning" with "no merit." *Id.* Moreover, the Court of Appeals has said that "[e]quivalence and non-equivalence, as the terms indicate, are but opposite sides of the same coin." *SRI Intern. v. Matsushita Elec. Corp of America*, 775 F.2d 1107, 1125 (Fed. Cir. 1985). While choosing to excise the reverse doctrine of equivalents from precedential case law, that court continues to apply the doctrine of equivalents regardless of the existence of § 112. The Court of Appeals for the Federal Circuit has stated: "The record is clear on why paragraph six was enacted . . . Congress enacted paragraph six, originally paragraph three, to statutorily overrule [the Supreme Court's] holding" in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 67 S.Ct. 6, 91 L.Ed. 3 (1946). *In re Donaldson* at 1194. Thus, as there is no evidence that Congress intended §112 to codify the doctrine, neither is there evidence that such was the *result*.

The Federal Circuit's uncertainty regarding the reverse doctrine of equivalents has fed confusion amongst the United States district courts as well. For example, the District Court for the District of Delaware guardedly wrote that "while the Federal Circuit has hinted that it may well be that Section 112 is a codification of the reverse doctrine of equivalents, it has never expressly held so . . . Until the Federal Circuit explicitly disregards the doctrine, the Court must presume its continued viability." *Ciena Corp. v. Corvis Corp.*, 334 F.Supp.2d 598, 604 (D. Del. 2004). Similarly, the United

States District Court for the District of Massachusetts cited *Tate* in opining that "the reverse doctrine of equivalents is. . . arguably moribund." *Depuy Spine, Inc. v. Medtronic Sofamar Danek, Inc.*, 53 F.Supp.2d 243, 246 (D. Mass. 2008) (citing *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1368 (Fed.Cir.2002)). These holdings evidence an uncertainty among the district courts regarding the continued viability of the doctrine and the effect of the Federal Circuit's holdings regarding the doctrine's application.

The confusion regarding the continued existence of the reverse doctrine of equivalents goes further still. Despite its proclamation in *Tate*, the Court of Appeals for the Federal Circuit, in *SRI*, supra, (Fed. Cir. 1985), recognized the reverse doctrine of equivalents and reversed a lower court's grant of summary judgment because of the existence of testimony precisely analogous to the testimony in the present case. The court stated plainly in *SRI* that "[i]t is settled that the question of infringement (literal or by equivalents) is factual. It would be anomalous to hold that the question of noninfringement (literal or by the reverse doctrine of equivalents) is not factual." *Id* (internal citation omitted). The court went on to expressly state that "[t]he genuine and material fact question of whether [defendant's devices] are 'so far changed in principle' that they 'perform the same or similar function in a substantially different way' being present and disputed, the district court erred in granting summary judgment." *Id* at 1126. Petitioner's record evidence here shows that Petitioner's chemical formulation is so far changed from the principle of Respondent's patent as to perform the same or similar function in a substantially different way.

Respondent disagrees with this position. As such, a genuine issue of material fact is present and disputed and the grant and affirmance of summary judgment constitute clear error.

The Federal Circuit Court of Appeals' decision in the present matter rejects the reverse doctrine of equivalents, again parting ways with the precedent of this Court as it did in *Tate*. The Court of Appeals for the Federal Circuit also rendered a decision here in direct conflict with its own precedent as found in *SRI*, where the court's recognition of the reverse doctrine of equivalents suggests that the court has *not* viewed 35 U.S.C. §112 as displacing the judicial doctrine. To allow these stark inconsistencies to remain unsettled – particularly in the court tasked with deciding all patent appeals – preserves substantial uncertainty as to the continued existence and methods of judicial application of the reverse doctrine of equivalents, an important doctrine of federal patent law. For this reason, Petitioner respectfully urges this Court to issue a writ of certiorari so that it may clarify the continuing confusion regarding this pressing question.

c. Petitioner has Presented Evidence Demonstrating the Principle of the '493 Patent and Further Demonstrating that Petitioner's Formulation is So Far Changed From That Principle as to Achieve its Function in a Substantially Different Way

This Court has held that in patent matters, in order to be judged liable, an

> "alleged infringer must have done something more than reach the same result. He must have reached it by substantially the same or similar means . . . To say that the patentee of a pioneer invention . . . is entitled to every device which produces the same result is to hold, in other language, that he is entitled to patent his function. Mere variations of form may be disregarded, but the substance of the invention must be there."

Boyden Power-Brake Co. at 170 U.S. at 569, 18 S.Ct. at 723. That is, "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim" the accused device does not infringe. *Graver Tank* at 339 U.S. at 608-9, 70 S.Ct. at 856.

Here, Petitioner presented an unrebutted expert declaration stating that the principle of Respondent's patent was the creation of robust stability by the formation of micelles using Octoxynol 40 (O_{40}) and that Petitioner's product was so far changed from that

principle that it achieved stability in a substantially different way, negating equivalence. Decl. of Ashim K. Mitra "A finding of equivalence is a determination of fact." *Graver Tank* at 339 U.S. at 609, 70 S.Ct. at 857. In view of Petitioner's evidence, the Court of Appeals for the Federal Circuit therefore should have reversed the district court's grant of summary judgment and ordered the district court to proceed to trial so that the fact finder be required to consider the reverse doctrine of equivalents and analyze the question in a manner consistent with the precedent of the Court of Appeals for the Federal Circuit and the precedent of this Court. The Court of Appeals did not do so and its decision calls for review and explication by this Court in order to make clear the current applicability of the reverse doctrine of equivalents.

II. The Court of Appeals Affirmed the Grant of Summary Judgment Based Upon Unsubstantiated Assertions of Plaintiffs' Attorneys and Failed to Believe Non-Movant Petitioner's Evidence or Draw All Reasonable Inferences From that Evidence in Petitioner's Favor, Contrary to the Binding Precedent of this Court

a. In Reviewing a Motion for Summary Judgment All Justifiable Inferences Are to Be Drawn in Favor of the Non-Moving Party

This Court's holding in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2505 (1986), has long stood as the standard for summary judgment. The teaching of its precedent is clear.

> "Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment 'shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'"

Id. at 477 U.S. at 247, 106 S.Ct. at 2509-10.

"In the . . . context of summary judgment under Rule 56 . . . the court must review the record 'taken as a whole.'" *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150, 120 S.Ct. 2097, 2110 (2000) (quoting *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986)). That is, "the court should review all of the evidence in the record," *Id.*, when considering a motion for summary judgment. "[T]he [non-movant], to survive the...motion, need only present evidence from which a jury might return a verdict in his favor. If he does so, there is a genuine issue of fact that requires a trial." *Anderson* at 477 U.S. at 257, 106 S.Ct. at 2514. "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 477 U.S. at 255, 106 S.Ct. at 2513

b. Petitioner Proffered Evidence Sufficient To Support Its Defense Of Noninfringement Under The Reverse Doctrine Of Equivalents Which Should Have Been Believed By The Lower Courts

The district court properly stated that in order "to prevail on [its] reverse doctrine of equivalents defense, [Petitioner] must as a threshold matter establish a 'principle' of the patented invention by reference to the claim language, specification, prosecution history, and/or prior art that this Court can then compare to the principle of the accused product." Op. at 6 (citations omitted) (App. C at 30a-31a). The district court held that Petitioner had not met this burden because Petitioner did not "identify any support for [its] proposed 'principle' of the '493 invention in the patent's claim language, specification, or prosecution history, nor in the prior art." Op. at 6-7 (App. C at 31a). This holding was affirmed by the Court of Appeals for the Federal Circuit. However, Petitioner did, through the declaration of its expert, proffer a principle of the invention and point to support for that principle. This evidence was to be believed by the court when evaluating Respondent's motion for summary judgment.

Petitioner's expert, Dr. Mitra, expressly stated that the claims and specification of the '493 patent disclosed to a person of ordinary skill in the art that the principle of the '493 invention was the creation of robust stability by the formation of micelles using O_{40} thereby preventing

interaction between charged ions in the formulation. Dr. Mitra opined:

> To one skilled in the art, Apotex' 0.4% ANDA formulation would not infringe the claims of the '493 patent under the reverse doctrine of equivalents because the concentration of O_{40} that is used in Apotex' formulation does not form micelles to solubilize and/or stabilize the KT/BAC complex . . .
>
> It is the NaCl, which is added to adjust tonicity of the formulation, that is serving the function of a stabilizer by forming the tightly bound ionic shielding around the KT and BAC ions thereby preventing them from interacting and forming a water insoluble complex.

Decl. of Ashim K. Mitra at ¶ 45-46.

Dr. Mitra's declaration clearly supports the position that Petitioner's composition acts in a manner so far changed from that principle as to achieve its function in a substantially different way. Decl. of Mitra at ¶ 31, ¶ 45. Specifically, Petitioner's formulation achieves stability not by forming micelles, but rather the formulation is cleared through the method of ionic shielding, with the addition of sodium chloride. Decl. of Mitra at ¶ 41, ¶ 46. In fact, O_{40} serves no function at all in Petitioner's formulation. Decl. of Mitra at ¶ 41, ¶45. Thus, Dr. Mitra's declaration fully supports Petitioner's defense of noninfringement under the reverse doctrine of equivalents, a genuine issue of material fact, which

may not be decided on summary judgment. As this Court stated in *KSR v. Teleflex*, 127 S.Ct. 1727, 1745 (2007), "[i]n considering summary judgment . . . the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact." The lower courts here did not. Instead, the district court and the Court of Appeals wholly disregarded this evidence.

While the lower courts overlooked Dr. Mitra's declaration in deciding the motion for summary judgment, the support cited by Petitioner and Dr. Mitra was set forth in the district court's prior fact findings, which remain the "law of the case." In its Findings of Fact and Conclusions of Law, the United States District Court for the Northern District of California found that "solutions containing Octoxynol 40 had better 'robust' stability under a variety of conditions than did the solutions containing" other nonionic surfactants. Findings of Fact, ¶ 32. Moreover, the court pointed out that during prosecution Respondents "narrowed the claims [of the '493 patent] to just the use of Octoxynol 40," *Id* at ¶ 33, relying on the stabilizing effect of O_{40} to achieve patentability over the prior art. The court took note of this, citing Respondent's prosecution of the '493 patent, during which Respondent's attorney stated in a September 5, 1991 amendment to the Patent Office that Octoxynol 40's superiority was demonstrated in that "other nonionic surfactants, such as Tween and Myrj, fail to act as stabilizers in the claimed formulations." *Id* at ¶ 38. As a result of this amendment, "[t]he examiner mailed a notice of allowance of all claims on December 3, 1991." *Id* at ¶ 43. Consistent with these

findings by the district court, Petitioner has offered, by evidence including the declaration of Dr. Mitra, the above-stated principle of the '493 patent and the opinion that Petitioner's formulation is so far changed from that principle as to achieve its function in a substantially different way.

By making these offerings, Petitioner met its burden for surviving summary judgment. The evidence presented must therefore be presented to the fact finder. For the lower courts to grant and affirm summary judgment required them to weigh the evidence presented to them and may only be viewed as an improper determination regarding the credibility of the proffered expert testimony. Rather, the lower courts should have drawn all reasonable inferences from that testimony in favor of Petitioner, the non-movant, denying the motion for summary judgment and proceeding to trial. The holdings of the lower courts are therefore clearly erroneous.

c. Respondent Failed to Challenge Petitioner's Offered Principle of the '493 Patent and Therefore a Question of Fact Exists

Petitioner's presentation of the uncontroverted expert declaration of Dr. Mitra, has met its burden of demonstrating the existence of a genuine issue of material fact. For Respondent to ignore that evidence does not undo its existence, nor should it be rewarded with a grant of summary judgment. As Mr. Justice Holmes once wrote, "[t]his is not a matter for polite presumptions; we must look facts in the face." *Frank v. Mangum*, 237 U.S. 309, 349, 35 S.Ct. 582, 595

(1915). Turning a blind eye to a question of fact and remaining silent should not be endorsed as a method of negating the existence of the issue.

"[A] litigant's failure to buttress its position because of confidence in the strength of that position is always indulged in at the litigant's own risk." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 897, 110 S.Ct. 3177, 3193 (1990). Here, Respondent failed to cast even the slightest doubt upon Petitioner's evidence, presumably under the belief that to argue the matter may demonstrate that an issue of fact exists and that to ignore it would give the illusion that no such issue exists. Petitioner has presented a genuine issue of fact in this matter and has supported its position regarding that issue through science and expert testimony. For this reason, the decisions of the district court and the Court of Appeals are clearly erroneous in view of the long-standing precedent of this Court and should be reversed.

CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that its Petition for a Writ of Certiorari be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED JULY 9, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1021

ROCHE PALO ALTO LLC (formerly known as Syntex (U.S.A.) LLC) and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants-Appellants.

Appeal from the United States District Court for the Northern District of California in case no. 05-CV-2116, Judge Martin J. Jenkins

DECIDED: July 9, 2008

Before MICHEL, *Chief Judge*, PROST, *Circuit Judge*, and HOCHBERG, *District Judge*.*

* Honorable Faith S. Hochberg, District Judge, United States District Court for the District of New Jersey, sitting by designation.

Appendix A

PROST, *Circuit Judge.*

This is a patent infringement case under the Hatch-Waxman Act. Apotex, Inc. and Apotex Corp. (collectively "Apotex") appeal the grant of summary judgment by the United States District Court for the Northern District of California that the patent held by Roche Palo Alto LLC and Allergan, Inc. (collectively "Roche") is valid and infringed by the formulation covered by Apotex's abbreviated new drug application ("ANDA"). *Roche Palo Alto, LLC v. Apotex, Inc.*, 526 F.Supp.2d 985 (N.D.Cal.2007). Because we find no error in the court's holding that the reverse doctrine of equivalents is inapplicable and that claim preclusion prohibits Apotex from raising other validity challenges, we affirm.

I

A

Roche is the owner of U.S. Patent No. 5,110,493 ("the '493 patent"), which is directed to a drug formulation for treatment of eye inflammation, such as that caused by glaucoma, conjunctivitis, eye surgery, or eye injury. '493 patent, col. 1, ll. 14-28. The formulation contains a non-steroidal anti-inflammatory drug ("NSAID"), such as ketorolac tromethamine ("KT"); a quaternary ammonium preservative, such as benzalkonium chloride ("BAC"); and the nonionic surfactant, octoxynol 40 ("O_{40}"). *Id.*, col. 3, ll. 13-19, col. 4, ll. 20-41. Claim 1 is representative:

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An opthalmologically acceptable non-steroidal anti-inflammatory drug formulation, comprising:

> an opthamologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug in an effective amount for ophthalmic treatment between 0.001 % and 10.00% wt/vol;
>
> a quaternary ammonium preservative in an antimicrobially effective amount between 0.001% and 1.0% wt/vol;
>
> an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2\text{-}CH_2)_n OH$ where *n* has an average value of 40 [O_{40}] in a stabilizing amount between 0.001% and 1.0% wt/vol; and an aqueous vehicle q.s. to 100%.

Dependent claim 7 further includes sodium chloride ("NaCl") at a concentration of 0.79% wt/vol.

The last limitation in claim 1, requiring the presence of O_{40}, was added in response to the examiner's obviousness rejection over several prior art references. Accompanying the claim amendment, the applicants submitted the Lidgate Declaration, which stated that

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O_{40} produced unexpected results over other nonionic surfactants, such as O_3 and O_5. Specifically, the declaration stated that O_{40} produced a clear solution while the others did not. The examiner allowed the claims based on the unexpected results of O_{40}.

Over the years, Apotex filed two different ANDAs on two different generic drug formulations, each containing a paragraph IV certification that the '493 patent is invalid, unenforceable, or will not be infringed by the generic version of the drug. In 2001, Apotex filed its first ANDA ("ANDA-1"), directed to a generic version of Roche's ACULAR®. Subsequently, in 2005, Apotex filed its second ANDA ("ANDA-2"), directed to a generic version of Roche's ACULAR®LS. The two formulations differ in their compositions as follows:

	ANDA-1 (ACULAR®)	ANDA-2 (ACULAR®LS)
KT	0.5%	0.4%
BAC	0.01%	0.0063%
O_{40}	0.01%	0.004%
NaCl	0.8%	0.8%

Notably, the concentration of O_{40} is reduced in the ANDA-2 formulation as compared to the ANDA-1 formulation, but both are within the range claimed in claim 1 of the

'493 patent. The concentration of NaCl is identical in the two formulations and encompassed by at least claim 1 of the patent.

B

On June 6, 2001, Roche's predecessor, Syntex (U.S.A.) LLC ("Syntex") sued Apotex for infringement of the '493 patent based on the ANDA-1 formulation. The district court issued a claim construction order. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, No. 01-2214 (N.D.Cal. Nov. 19, 2002). Because claim 1 of the '493 patent expressly states a concentration range for O_{40}, the court held that the claim term "stabilizing amount" is merely a statement of intended result and not a claim limitation. *Id.*, slip op. at 9. Thereafter, the district court granted Syntex's motion for partial summary judgment that the ANDA-1 formulation literally infringed the '493 patent. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, No. 01-2214, slip op. at 4-5 (N.D.Cal. Mar. 19, 2003). Following a bench trial on Apotex's invalidity defenses of lack of utility, lack of enablement, indefiniteness, and obviousness, and its unenforceablity defense based on inequitable conduct, the court held that the '493 patent was both valid and enforceable. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, No. 01-2214 (N.D.Cal. Dec. 29, 2003) ("*Syntex I*").

On May 18, 2005, this court affirmed the district court's claim construction and holding of no inequitable conduct, but reversed its holding of validity based on non-obviousness. *Syntex (U.S.A.) LLC v. Apotex, Inc.*,

407 F.3d 1371 (Fed.Cir.2005) ("*Syntex II* "). Specifically, we found that the district court clearly erred in some of its factual findings and misapplied certain legal presumptions with respect to its obviousness analysis. *Id.* at 1378-83. On remand, the district court again held that the '493 patent was not invalid for obviousness, *Syntex (U.S.A.) LLC v. Apotex, Inc.*, No. 01-2214, 2006 WL 1530101 (N.D.Cal. June 2, 2006) ("*Syntex III*"), and we affirmed without opinion. 221 Fed.Appx. 1002 (Fed.Cir. Apr. 9, 2007).

One day after our mandate issued, the Supreme Court issued its opinion on obviousness in *KSR International Co. v. Teleflex Inc.*, __ U.S. __, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). Apotex then filed a motion to recall and stay the mandate, and to extend the time to request a rehearing in view of *KSR*, but the motion was denied. Apotex also filed a petition for writ of certiorari, and that petition too was denied. *Apotex, Inc. v. Syntex (U.S.A.) LLC*, __ U.S. __, 128 S.Ct. 209, 169 L.Ed.2d 146 (2007).

C

On May 24, 2005, Roche sued Apotex for infringement of the '493 patent based on the ANDA-2 formulation. Apotex asserted the defenses of non-infringement; invalidity under 35 U.S.C. §§ 101, 103, and 112; and unenforceability due to inequitable conduct. Thereafter, Roche filed a motion for summary judgment that the ANDA-2 formulation infringes the '493 patent and that the validity and unenforceability defenses

should be barred based on the earlier Syntex litigation (*Syntex I*, *Syntex II*, and *Syntex III*) under the doctrines of issue preclusion and claim preclusion. Apotex countered by arguing that the ANDA-2 formulation escapes infringement under the reverse doctrine of equivalents. Apotex further averred that the doctrines of issue preclusion and claim preclusion were inapplicable because the ANDA-2 formulation and the ANDA-1 formulation were distinct, and the change in law exception, in view of *KSR*, prevented application of those doctrines.

On September 11, 2007, the district court granted Roche's motion for summary judgment. *Roche Palo Alto LLC v. Apotex, Inc.*, 526 F.Supp.2d 985 (N.D.Cal.2007). First, the court found that Apotex had failed to properly establish the "principle" of the '493 invention under the first prong of the reverse doctrine of equivalents analysis. *Id.* at 992-93. Although Apotex contended that the "principle" of the invention was to use O_{40} to provide robust stability to the formulations by forming micelles to prevent interaction between KT and BAC, the court noted that Apotex did not support this "principle" by reference to the claim language, specification, prosecution history, and/or prior art, which are the proper sources to determine the equitable scope of the claims. *Id.* Therefore, the court held that Apotex did not meet its burden of establishing a prima facie case of noninfringement under the reverse doctrine of equivalents. *Id.*

The district court also held that Apotex's invalidity and unenforceablity arguments, with the exception of obviousness, were prevented by issue preclusion because the invalidity of the '493 patent had already been asserted against Roche in the ANDA-1 litigation. *Id.* at 994-95. Following Ninth Circuit precedent, the court held that issue preclusion barred Apotex from challenging validity on any ground, even grounds that had not been raised in the first litigation. *Id.* at 995. With respect to the validity challenge on obviousness grounds, the court did not reach whether the Supreme Court decision in *KSR* constituted a change in law necessitating an exception to issue preclusion because it held that such a challenge was prevented by claim preclusion. *Id.* at 997.

With respect to claim preclusion, the district court held that the two accused products, ANDA-1 and ANDA-2, are "essentially the same," and thus each of the invalidity claims in the ANDA-2 litigation was prevented by claim preclusion. *Id.* at 997-99. The court further held that there is no "change of law" or fairness exception to claim preclusion to prevent its application despite the intervening *KSR* decision. *Id.* at 999-1000. Hence, the court held that Apotex's invalidity and unenforceability affirmative defenses were barred by claim preclusion. *Id.* at 1000.

Apotex appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

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II

We review a grant of summary judgment of non-infringement de novo, reapplying the standard used by the district court. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed.Cir.2008). Summary judgment is appropriate where, drawing all reasonable inferences in favor of the non-movant, there is no genuine issue as to any material fact and no reasonable jury could return a verdict for the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The determination of infringement is a two-step process, wherein the court first construes the claims and then determines whether every claim limitation, or its equivalent, is found in the accused device. *In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1259 (Fed.Cir.2007). While claim construction is a question of law that we review de novo, *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed.Cir.1998) (en banc), non-infringement under the reverse doctrine of equivalents is a question of fact. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1124 (Fed.Cir.1985).

We review the district court's application of the doctrine of claim preclusion de novo. *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1322-24 (Fed.Cir.2008); *Maldonado v. Harris*, 370 F.3d 945, 949 (9th Cir.2004); *Littlejohn v. United States*, 321 F.3d 915, 919 (9th Cir.2003).

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III

Apotex does not dispute that the ANDA-2 formulation falls within the literal scope of claim 1 of the '493 patent. Instead, Apotex argues that the district court erred in failing to find non-infringement by the ANDA-2 formulation under the reverse doctrine of equivalents.

The reverse doctrine of equivalents is an equitable doctrine designed "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed.Cir.1991). According to the Supreme Court:

> [W]here a device is so far changed in *principle* from a patented article that it performs the same or similar function in a *substantially different way,* but nevertheless falls within the literal words of the claim, the [reverse] doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-609, 70 S.Ct. 854, 94 L.Ed. 1097 (1950) (emphases added). While the patentee bears the burden of proving infringement, if the patentee establishes literal infringement, the burden shifts to the accused infringer to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents.

SRI Int'l, 775 F.2d at 1123-24. If the accused infringer is successful in making a prima facie case, the patentee must then rebut that prima facie case. *Id.* at 1124. The reverse doctrine of equivalents is rarely applied, and this court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1368 (Fed.Cir.2002).

Apotex, relying on the declaration of its scientific expert, Dr. Mitra, argues that a person of ordinary skill in the art would recognize that the "principle" of the '493 patent is the use of O_{40} in an amount sufficient to cause the formation of micelles and thereby provide robust stability to the formulation by preventing interactions between KT and BAC. Apotex contends that such a principle is supported by the prosecution history of the '493 patent application in that the examiner ultimately allowed the claims based on the Lidgate Declaration, demonstrating the unexpected results of formulations containing O_{40}. According to Apotex, it is of no consequence that the claims, specification, and prosecution history do not mention "micelles" and that the district court construed "stabilizing amount" to be an intended result, not a claim limitation, since a person of ordinary skill in the art knows that O_{40} stabilizes the formulation by forming micelles. In contrast to the patented invention, Apotex asserts, the concentration of O_{40} in the ANDA-2 formulation is far below the concentration required to form micelles. Instead, in the ANDA-2 formulation, NaCl acts to ionically shield KT and BAC, preventing them

from interacting. Thus, Apotex asserts, the ANDA-2 formulation is stabilized by a completely different ingredient and mechanism, and functions in a "substantially different way" from the formulation claimed in the '493 patent.

Apotex contends that because it has succeeded in making a prima facie showing of non-infringement under the reserve doctrine of equivalents, it is incumbent upon Roche to rebut that prima facie case. According to Apotex, Roche has presented only attorney arguments, not scientific evidence or expert testimony, to rebut Apotex's evidence. Even if the attorney arguments are accepted as contrary evidence, Apotex contends that there is at least a genuine issue of material fact in dispute not amenable to resolution on summary judgment. Thus, Apotex asserts, the district court erred by not drawing all inferences in favor of Apotex and not finding a genuine issue of material fact.

We agree with the district court that Apotex has failed to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents because it does not properly establish the principle of the '493 patent. The "principle" or "equitable scope of the claims" of the patented invention is determined in light of the specification, prosecution history, and the prior art. *Scripps Clinic*, 927 F.2d at 1581. Here, however, Apotex relies exclusively on the declaration of its expert, Dr. Mitra.

As the district court noted, there is no mention of "micelle" in the claims, specification, or prosecution history of the '493 patent. Further, we previously held that there was no error in the district court's construction of claim 1 of the '493 patent to regard "stabilizing amount" not as a claim limitation, but as an intended result, given that the claim expressly sets forth a concentration range for O_{40}. *Syntex II*, 407 F.3d at 1378. Thus, there is no support in the claims or specification for micelle formation or for robust stabilization of the formulation by prevention of KT/BAC interactions. The prosecution history is not in evidence in this case and was not relied on by Apotex before the district court in establishing the principle of the invention. Nonetheless, there is no indication that the examiner, in allowing the claims, attributed the unexpected results of O_{40} to its superiority in forming micelles. The intrinsic evidence is therefore inconsistent with Apotex's proffered "principle" of the '493 invention.

The claims and the specification clearly encompass formulations comprising a broad concentration range of O_{40}, from 0.001% to 10% wt/vol.[1] Example 3 discloses a

1. Apotex asserts that, if the '493 claims are construed to cover the entire claimed O_{40} concentration range, then the claims are invalid under 35 U.S.C. § 112, first paragraph, because they are not enabled throughout their full scope. Alternatively, Apotex argues that, if the claims are so construed, they are invalid as obvious under 35 U.S.C. § 103, because not all concentrations form micelles and thus produce unexpected results. Such arguments go to the validity of the claims of the (Cont'd)

formulation containing O_{40} at a concentration of 0.004% wt/vol, the same concentration as in the ANDA-2 formulation.

For these reasons, we agree with the district court that Apotex did not properly support its alleged "principle" of the patented invention and consequently failed to make out a prima facie case of non-infringement under the reverse doctrine of equivalents. Roche, therefore, was not required to rebut the prima facie case. Accordingly, we find no error by the district court in rejecting Apotex's defense under the reverse doctrine of equivalents and in granting summary judgment of literal infringement of the claims of the '493 patent by the ANDA-2 formulation.

IV

Apotex next asserts that the district court erred in holding that its validity challenges to the '493 patent were barred by claim preclusion. Under Ninth Circuit law, claim preclusion applies where: "(1) the same parties, or their privies, were involved in the prior litigation, (2) the prior litigation involved the same claim or cause of action as the later suit, and (3) the prior litigation was terminated by a final judgment on the merits." *Cent. Delta Water Agency v. United States*, 306

(Cont'd)

'493 patent. For the reasons discussed below, we agree with the district court that such validity challenges are barred by claim preclusion.

F.3d 938, 952 (9th Cir.2002) (citing *Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313, 323-24, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971)); *Mpoyo v. Litton Electro-Optical Sys.*, 430 F.3d 985, 987 (9th Cir.2005).

Apotex does not dispute that the *Syntex* litigation (*Syntex I*, *Syntex II*, and *Syntex III*) ended in a final judgment and that it involved the same parties or their privies. Rather, Apotex contests only the district court's holding that the instant litigation, pertaining to its ANDA-2 formulation, and the *Syntex* litigation, pertaining to its ANDA-1 formulation, involved the same claim or cause of action. Whether two claims for infringement constitute the "same claim" is an issue particular to patent law and thus Federal Circuit law applies. *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1322-24 (Fed.Cir.2008); *Hallco Mfg. Co. v. Foster*, 256 F.3d 1290, 1294 (Fed.Cir.2001). Under the law of the Federal Circuit, an infringement claim in a second suit is the "same claim" as in an earlier infringement suit if the accused products in the two suits are "essentially the same." *Acumed*, 525 F.3d at 1324; *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 479-80 (Fed.Cir.1991). Accused products "are 'essentially the same' where the differences between them are merely 'colorable' or 'unrelated to the limitations in the claim of the patent." *Acumed*, 525 F.3d at 1324 (citations omitted); Foster, 947 F.2d at 480. The party asserting claim preclusion has the burden of showing that the accused products are essentially the same. *Acumed*, 525 F.3d at 1324; *Foster*, 947 F.2d at 480.

Apotex avers that Roche had the burden of establishing that the ANDA-2 formulation at issue in the instant litigation and the ANDA-1 formulation at issue in the *Syntex* litigation were "essentially the same," yet Roche did not present any expert testimony or other evidence to that effect. In contrast, Apotex provided the Mitra Declaration, which shows that the concentration of O_{40} in the ANDA-2 formulation is insufficient to form micelles and thus the ANDA-2 formulation is materially different from the ANDA-1 formulation. Apotex further contends that the ANDA-2 formulation is not "essentially the same" as the ANDA-1 formulation because the two formulations are stabilized by completely different ingredients and mechanisms. Whereas micelle formation by O_{40} stabilizes the ANDA-1 formulation, ionic shielding by NaCl stabilizes the ANDA-2 formulation. According to Apotex, the fact that it had to file a separate ANDA for the ANDA-2 formulation is additional evidence that the ANDA-2 formulation is materially different from the ANDA-1 formulation. Thus, Apotex asserts that there is at least a genuine issue of material fact as to whether the two ANDA formulations are "essentially the same."

We find no error in the district court's analysis. The court determined that the ANDA-1 formulation and the ANDA-2 formulation are "essentially the same" because any differences between them are unrelated to the claims of the '493 patent. Though the court recognized that there are differences in the concentrations of the ingredients in the ANDA-1 and ANDA-2 formulations, it also realized that all of the concentrations are well

within the ranges claimed in the '493 patent. The fact that they are stabilized by different mechanisms, even if true, is irrelevant because both formulations are encompassed by the claims of the '493 patent. Thus, any difference in composition between the two formulations is merely colorable and the two formulations are "essentially the same."

In the alternative, Apotex asserts that principles of fairness should prevent application of claim preclusion given the change in the law of obviousness following the Supreme Court's opinion in *KSR*. In essence, Apotex argues that claim preclusion is not absolute and that this is a case where an exception to the finality rule should apply.

The district court, however, correctly recognized that there is no "change of law" or fairness exception to prevent application of claim preclusion. *Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 398, 101 S.Ct. 2424, 69 L.Ed.2d 103 (1981); *see also Clifton v. Att'y Gen. of Cal.*, 997 F.2d 660, 663 (9th Cir.1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); *Wilson v. Lynaugh*, 878 F.2d 846, 850-51 (5th Cir.1989); *Precision Air Parts, Inc. v. Avco Corp.*, 736 F.2d 1499, 1503 (11th Cir.1984) ("The general rule . . . throughout the nation, is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled."); *Hardison v. Alexander*,

655 F.2d 1281, 1288-89 (D.C.Cir.1981). Although there may be a rare exception in cases involving "momentus changes in important, fundamental constitutional rights," *Precision Air Parts*, 736 F.2d at 1504, no such right is involved here.

As the Supreme Court explained:

> Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case. . . . We have observed that "[t]he indulgence of a contrary view would result in creating elements of uncertainty and confusion and in undermining the conclusive character of judgments, consequences which it was the very purpose of the doctrine of res judicata to avert."

Federated Dep't Stores, 452 U.S. at 398-99, 101 S.Ct. 2424 (citations and internal quotations omitted). Thus, the *KSR* decision does not prevent application of claim preclusion.

Accordingly, the district court did not err in concluding that Apotex's validity challenges to the '493 patent were barred by the doctrine of claim preclusion.[2]

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2. Because we hold that the district court properly determined that Apotex's validity challenges were barred by claim preclusion, we need not reach whether the district court lawfully applied the doctrine of issue preclusion to bar the same validity challenges.

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V

For the foregoing reasons, we affirm the district court's grant of Roche's motion for summary judgment that the ANDA-2 formulation literally infringes the claims of the '493 patent and that Apotex's invalidity and unenforceability challenges to the '493 patent are barred by claim preclusion.

AFFIRMED.

APPENDIX B — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION DATED SEPTEMBER 21, 2007

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Case No.: 3:05-cv-02116-MJJ

Related Case:
Case No.: 3:01-cv-02214-MJJ

ROCHE PALO ALTO LLC, formerly known as SYNTEX (U.S.A.) LLC, a Delaware corporation, and ALLERGAN, INC., a Delaware corporation,

Plaintiffs,

v.

APOTEX, INC., a Canadian corporation, and APOTEX CORP., a Delaware corporation,

Defendants.

[~~PROPOSED~~] JUDGMENT

Judge: Hon. Martin J. Jenkins

This action came on for hearing on Plaintiffs' Motion for Summary Judgment (Docket No. 52) on August 31, 2007, the Honorable Martin J. Jenkins presiding. The

Appendix B

Court having considered Plaintiffs' Motion for Summary Judgment and the papers and pleadings submitted in support thereof, Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and the papers and pleadings submitted in support thereof, as well as the argument of counsel and the papers and pleadings on file in this case;

It is Ordered and Adjudged:

(1) that Defendants, and each of them, have infringed claims 1-5 and 15-16 of United States Patent No. 5,110,493 ("the '493 patent") by the filing of Abbreviated New Drug Application No. 77-308;

(2) that the '493 patent is enforceable and the claims of the '493 patent are not invalid;

(3) that the effective date of any approval by the Food and Drug Administration of Abbreviated New Drug Application No. 77-308 shall be a date not earlier than the expiration date of the '493 patent;

(4) that Plaintiffs shall recover from Defendants, and each of them, their costs in this action.

Dated at San Francisco, California, this 21st day of September, 2007.

s/ Martin J. Jenkins
Judge Martin J. Jenkins

APPENDIX C — ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA DATED SEPTEMBER 11, 2007

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C05-02116 MJJ

ROCHE PALO ALTO LLC ET AL,

Plaintiff,

v.

APOTEX, INC. ET AL,

Defendant.

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Before the Court is Plaintiffs Roche Palo Alto LLC and Allergan, LLC's Motion For Summary Judgment. (Docket No. 52.)

For the following reasons, the Court **GRANTS** the Motion, as described in more detail below.

Appendix C

FACTUAL BACKGROUND

This case involves the same parties, and the same patent, as a previous matter litigated to judgment before this Court: *Syntex v. Apotex*, Case No. 3:01-cv-02214 MJJ (*"Syntex"*). As with *Syntex*, this case is about Defendants' proposal, in an Abbreviated New Drug Application ("ANDA") filed with the FDA, to make and sell a ketorolac tromethamine ("KT") ophthalmic solution, and whether that solution would infringe U.S. Patent No. 5,110,493 ("the '493 Patent") under 35 U.S.C. § 271(e)(2).

A. The Prior *Syntex* Litigation.

In the earlier *Syntex* litigation, Plaintiffs filed a complaint alleging that Defendants' ANDA 76-109 formulation infringed the '493 Patent. The drug for which Defendants sought approval pursuant to ANDA 76-109 was a 0.5% KT ophthalmic solution that was a generic copy of a 0.5% KT ophthalmic solution marketed by Plaintiffs known as ACULAR®. In *Syntex*, Defendants disputed whether their ANDA 76-109 formulation infringed the '493 Patent, and also argued (in the form of both affirmative defenses and counterclaims) that the '493 Patent was invalid and unenforceable. Specifically, with respect to invalidity, Defendants contended that the '493 patent was invalid on the grounds that it lacked utility, lacked enablement, failed to disclose the best mode, was indefinite, and was obvious. With respect to unenforceability, Defendants contended that Plaintiffs had committed inequitable conduct in prosecuting the '493 Patent.

Appendix C

After issuing a claim construction order, this Court granted summary judgment of infringement in favor of Plaintiffs in *Syntex*. The Court then conducted a bench trial on the issues of invalidity and unenforceability of the '493 Patent, and issued Findings of Fact and Conclusions of Law that determined that the '493 Patent was valid and enforceable.

On an appeal brought by Defendants, the Federal Circuit affirmed this Court's claim construction and determination that there was no inequitable conduct, but remanded the case to this Court for further consideration of obviousness. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed.Cir.2005). After further briefing and hearing on remand, this Court issued further Findings of Fact and Conclusions of Law in which it found, for a second time, that the '493 patent was not invalid based on obviousness. On a second appeal by Defendants, the Federal Circuit subsequently affirmed, in an April 9, 2007 order, this Court's determination that the '493 Patent is not invalid and is non-obvious.

On April 30, 2007, the Supreme Court issued its decision in *KSR International Co. v. Teleflex Inc.*, __ U.S. __, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007) addressing the standards by which obviousness should be adjudicated. On May 3, 2007, contending that the *KSR* decision constituted a change in the law of obviousness, Defendants filed a motion with the Federal Circuit requesting that the Federal Circuit recall and stay its mandate in Syntex and accept a petition for

rehearing by panel or *en banc*. The Federal Circuit summarily denied Defendants' motion on June 5, 2007. On July 9, 2007, Defendants filed a petition for a writ of certiorari with the United States Supreme Court, seeking to have the Federal Circuit's April 9, 2007 decision summarily vacated and remanded. That petition is still pending.

B. The Current Litigation.

In 2005, Defendants submitted a second ANDA (ANDA 77-308) to the FDA, seeking approval for an 0.4% KT ophthalmic solution which would be a generic copy of a 0.4% KT ophthalmic solution marketed by Plaintiffs known as ACULAR LS®. Plaintiffs filed the complaint in this action against Defendants in May 2005, alleging that the ANDA 77-308 formulation infringes the '493 Patent. In their amended answer, Defendants contend that the ANDA 77-308 formulation does not infringe. They also again argue (in the form of both affirmative defenses and counterclaims) that the '493 Patent is invalid and unenforceable. With respect to invalidity, Defendants this time contend that the '493 patent is invalid on the grounds that it lacks utility, lacks enablement, fails to disclose the best mode, is indefinite, is obvious, and constitutes obviousness-type double patenting. With respect to unenforceability, Defendants again contend that Plaintiffs committed inequitable conduct in prosecuting the '493 Patent.

Appendix C

LEGAL STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure authorizes summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The moving party bears the initial burden of demonstrating the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, affidavits, and admissions on file that establish the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the moving party meets this initial burden, the burden then shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. Fed.R.Civ.P. 56(e); *Celotex*, 477 U.S. at 324, 106 S.Ct. 2548; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The non-movant's bare assertions, standing alone, are insufficient to create a material issue of fact and defeat a motion for summary judgment. *Anderson*, 477 U.S. at 247-48, 106 S.Ct. 2505. An issue of fact is material if, under the substantive law of the case, resolution of the factual dispute might affect the case's outcome. *Id.* at 248, 106 S.Ct. 2505. Factual disputes are genuine if they "properly can be resolved in favor of either party." *Id.* at 250, 106 S.Ct. 2505. Thus, a genuine issue for trial exists if the non-movant presents evidence from which a reasonable jury, viewing the evidence in the light most favorable to that party, could resolve the material issue

in its favor. *Id.* However, "[i]f the [non-movant's] evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50, 106 S.Ct. 2505 (internal citations omitted).

ANALYSIS

A. Plaintiffs Are Entitled To Summary Judgment Of Infringement.

Submission of an ANDA is an act of patent infringement if the ANDA seeks approval for a drug that is claimed in a patent or the use of which is claimed in a patent. 28 U.S.C. § 271(e). Determination of patent infringement is a two-step analysis. The first step is to construe, or interpret, a claim of the patent. *See Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed.Cir.2001). The second step is to determine whether every limitation of the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See id.*

1. Defendants Do Not Dispute That Each Limitation Of Claims 1-5, 15 & 16 Literally Reads On The ANDA 77-308 Formulation.

Plaintiffs contend that Defendants have admitted, in responses to requests for admission, that all of the claim limitations contained in claims 1-5, 15 and 16 of the 493 Patent literally read on the ANDA 77-308 formulation. The Court agrees.

Appendix C

Determination of which terms in the '493 Patent claims constitute claim limitations, and construction of those terms deemed limitations, was previously addressed by this Court in *Syntex*. At that time, this Court determined that the Court determined that "stabilizing" and "antimicrobially effective" are not claim limitations, and arrived at constructions of the other limitations. Defendants do not challenge the correctness of this Court's prior claim construction rulings here, and in any event, issue preclusion would prevent Defendants from relitigating these claim construction issues. *See Del Mar Avionics, Inc. v. Guinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed.Cir.1987). The Court's claim constructions from *Syntex* are binding on Defendants.

Defendants also do not dispute that their responses to Plaintiffs' requests for admission admit that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); *id.*, Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); *id.*, Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16).) The Court therefore finds that it is undisputed that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation.

2. Because Defendants' Reverse Doctrine of Equivalents Argument Lacks Any Support In The Claims, Specification, Prosecution History or Prior Art, It Fails As A Matter Of Law.

Defendants contend that summary judgment of infringement is nonetheless inappropriate because they have raised a triable issue of fact as to whether the reverse doctrine of equivalents defense precludes a finding of infringement. The Court finds, however, that Defendants' reverse doctrine of equivalents argument lacks any support in the '493 Patent's claims, specification, prosecution history, or prior art, and therefore fails as a matter of law.

Under the reverse doctrine of equivalents, "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09, 70 S.Ct. 854, 94 L.Ed. 1097 (1950) (citations omitted). Once a patentee shows claims literally read on accused product, the burden of showing nonequivalence under this doctrine shifts to the accused infringer. *See Del Mar Avionics*, 836 F.2d at 1325 (Fed.Cir.1987) (finding accused infringer had not "carried the burden of its argument" when invoking the reverse doctrine of equivalents); *Tate Access Floors, Inc. v. Interface*

Architectural Resources, Inc., 279 F.3d 1357, 1368 (Fed.Cir.2002) (referring to reverse doctrine of equivalents as a "defense to literal infringement").[1]

The reverse doctrine of equivalents is an equitable doctrine that was judicially created to prevent unwarranted extension of the claims of a patent beyond a fair scope of the patentee's invention. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.3d 1565, 1581 (Fed.Cir.1991). The equitable scope, or "principle", of the invention must in the first instance be determined from evidence in the public record. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed.Cir.1991) ("Application of the [reverse doctrine of equivalents] requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, ***which in turn is determined in light of the specification, the prosecution history, and the prior art.***") (emphasis added). To prevail on their reverse doctrine of

1. The Court rejects Plaintiffs' contention that the reverse doctrine of equivalents defense is categorically inapplicable to disputes where chemical composition claims and/or generic copies of drugs are involved. While as a matter of logic such disputes leave very little leeway to determine that a product literally reads on the claim but is so far changed in principle from the claimed compound that it does not infringe, *see U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 n. 9 (Fed.Cir.1989), the defense still has viability under controlling Federal Circuit precedent. The Court will therefore examine whether Defendants have met their burden of establishing a triable issue of fact regarding applicability of the defense on this record.

equivalents defense, Defendants must as a threshold matter establish a "principle" of the patented invention by reference to the claim language, specification, prosecution history, and/or prior art that this Court can then compare to the principle of the accused product. *See Ciena Corp. v. Corvis Corp.*, 334 F.Supp.2d 598, 604-05 (D.Del.2004); *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 n. 9 (Fed.Cir.1989).

Here, Defendants contend that the "principle" of the '493 invention is the use of Octoxynol 40 to provide "robust" stability to the '493 formulations by forming micelles to prevent interaction between ketorolac tromethamine ("KT") and benzalkonium chloride ("BAC"). Defendants contend that their ANDA 77-308 formulation, in contrast, contains such a low concentration of Octoxynol 40 that it does not produce micelles that solubilize the KT/BAC complex; instead, Defendants contend, the NaCl in their formulation ionically shields the KT and BAC icons, prevents them from interacting, and stabilizes the formulation.

The fundamental problem with Defendants' contention—which this Court considers fatal to Defendants' efforts to withstand summary judgment of infringement—is that Defendants do not identify any support for their proposed "principle" of the '493 invention in the patent's claim language, specification, or prosecution history, nor in the prior art. It is these sources that determine the equitable scope of the claims. *See Scripps Clinic & Research Foundation* 927 F.2d at 1581. Yet Defendants point to nothing in the

patent claims, patent specification, prosecution history, or prior art that refer, even indirectly, to the use of Octoxynol 40 to provide stability to the '493 formulations by forming micelles to prevent KT/BAC interaction. Indeed, Defendants are unable to identify any place that the term "micelle" even appears in the patent's claims, specification, or prosecution history.

Defendants' contention regarding the "principle" of the '493 invention is also inconsistent both with the claim language (as construed by the Court in *Syntex*) and the '493 specification. With respect to the claim language, this Court has already ruled that "stabilizing amount" is not a claim limitation (Plaintiff's Request For Judicial notice (hereafter "RJN"), Exh. D), a finding that, as noted above, is binding on Defendants. Defendants' efforts to import into the invention a requirement that Octoxynol 40 be present in an amount that forms micelles and stabilizes the formulation contradicts this ruling, and is tantamount to an improper attempt to "reargue claim construction issues which were already rejected by the Court." *Ciena Corp.*, 334 F.Supp.2d at 608. Moreover, Example 3 in the specification discloses a formulation containing Octoxynol 40 in an amount of 0.004% wt/vol. (Shafroth Decl., Exh. 1 at 7:25-40), the very concentration that Defendants' expert contends cannot form micelles. (Mitra Decl., ¶¶ 34-37.) Thus, the specification itself is inconsistent with Defendants' underlying contention that the patent's central principle is for Octoxynol 40 to stabilize an interaction through micelle formation.

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Defendants rely exclusively on findings made by this Court regarding the *utility* of the '493 patent in the Syntex matter as their basis for establishing that the principle of the '493 invention is the use of Octoxynol 40 in an amount sufficient to achieve critical micelle concentration and form micelles. Specifically, Defendants and their expert, Dr. Mitra, assert that "a person of ordinary skill in the art reading the Court's December 29, 2003 Findings/Conclusions . . . would interpret them to mean that the function and purpose of O40 is to provide 'robust' stability to the '493 patent formulations by forming micelles to prevent the KT/BAC interaction." (Opp. at 7-8, *see also* Mitra Decl.¶¶ 25, 48.) This is plainly insufficient to meet Defendants' burden of proof regarding the equitable scope or "principle" of the '493 Patent's claims. The Court's factual findings on the issue of utility, and specifically the Court's factual findings regarding the function of Octoxynol 40 in the patented invention, were not directed towards determining the equitable scope of the '493 Patent's claims. More fundamentally, the Court's findings did not draw on the patent claims, patent specification, prosecution history, or prior art for evidentiary support. To the contrary, the Court's factual findings on the function of Octoxynol 40 were based on the evidence of expert tests, not found in the '493 file wrapper or the prior art, that were introduced by the parties into the record at the bench trial. Such evidence is simply not probative of the equitable scope of the '493 claims as issued. Defendants' reliance on this Court's prior factual findings is misplaced and cannot suffice to meet Defendants' burden of establishing the "principle" of the '493 invention.

Accordingly, Defendants' reverse doctrine of equivalents argument fails as a matter of law.[2] Summary judgment of infringement in favor of Plaintiffs is therefore appropriate.

B. Issue Preclusion Bars Defendants, At A Minimum, From Asserting Unenforceability As Well As All Invalidity Theories Other Than Obviousness.

Plaintiffs contend that issue preclusion bars Defendants from asserting in this action that the '493 Patent is unenforceable or invalid, because these issues were decided in the *Syntex* litigation.

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2. Because Defendants' reverse doctrine of equivalents argument fails at the threshold for the reasons stated above, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra, Defendants' expert, nor Plaintiffs' contention that issue preclusion bars Defendants from asserting their reverse doctrine of equivalents argument. The Court is troubled by the fact that Dr. Mitra's first declaration submitted in support of Defendants' opposition nowhere acknowledges that the critical micelle concentration ("CMC") Octoxynol 40 can vary depending on the ingredients present in the formulation, and contains several potentially misleading statements as a result. (August 13, 2007 Mitra. Decl. at ¶¶ 22-26, 37.) Nonetheless, because Defendants' reverse doctrine of equivalents argument fails for other reasons, the Court does not reach the question of whether Dr. Mitra's declaration rises to the level of a "sham" declaration that must be disregarded.

Appendix C

1. The Elements Of Issue Preclusion.

Issue preclusion (sometimes called collateral estoppel) bars relitigation of issues adjudicated in an earlier proceeding if three requirements are met: (1) the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated; (2) the first proceeding ended with a final judgment on the merits; and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding. *See Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 (9th Cir.2006).

The second and third requirements of this test are clearly met. The Defendants here were also parties to the *Syntex* litigation. In that earlier litigation, this Court decided that the '493 patent is enforceable and not invalid, and entered judgment to that effect. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants' still-pending petition writ of certiorari before the United States Supreme Court does not alter the preclusive effect of this Court's earlier judgment in *Syntex*. *See Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir.1988).

The applicability of issue preclusion therefore turns on the first element—whether the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated.

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With respect to enforceability of the '493 patent, Defendants do not dispute that the inequitable conduct defense/counterclaim they seek to assert in this litigation is identical to the unenforceability defense/counterclaim that they litigated and lost in Syntex. (*Compare* RJN, Ex. C at Counterclaim, ¶ ¶ 13-37 *with* Amended Answer at Counterclaim, ¶¶ 13-37 (Docket No. 23).) Accordingly, all elements of issue preclusion are met with respect to Defendants' unenforceability defense and counterclaim in this action. Issue preclusion therefore prevents Defendants from relitigating the '493 Patent's enforceability.

With respect to invalidity of the 2 493 patent, Defendants do not dispute that they already litigated the validity of the '493 patent in *Syntex*. However, Defendants contend that, for issue preclusion purposes, the only relevant "issues" that can qualify for issue-preclusive effect are the specific grounds for invalidity that Defendants asserted in *Syntex*. Plaintiffs counter that the relevant "issue" is the ultimate determination on patent validity itself, regardless of which sub-issues or specific grounds were asserted by Defendants in the previous litigation.

The authorities that have considered this question support Plaintiff's view and indicate that the relevant "issue" which Defendants are precluded from relitigating is the ultimate determination on patent validity itself. This Court is persuaded that the reasoning set forth in *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 352 F.Supp.2d 1119, 1124-26 (C.D.Cal.2005)

("*Applied*") regarding the applicability of issue preclusion in the patent invalidity context is correct. In *Applied*, applying Ninth Circuit precedent and the Second Restatement of Judgments, the district court held that the "issue" that the accused infringer was precluded from relitigating because of a prior judgment was the validity of the asserted patent claim. *Id.* at 1124-26 (citing *Kamilche Co. v. United States*, 53 F.3d 1059, 1062 (9th Cir.1995)). The district court held that what the accused infringer argued were the "issues"—specific arguments such as anticipation by prior sale, best mode, public use, and prior publication—were "just the particular arguments raised in support of [invalidity] in the first case." *Id.* at 1125. Applying Ninth Circuit precedent, *Applied* found that issue preclusion barred the accused infringer not only from re-raising any grounds on which it had argued invalidity in the first litigation, but also the invalidity grounds newly raised in the second litigation, such as prior art anticipation and obviousness. *See id.* at 1127-28. District courts from around the country are in agreement with the result reached in *Applied*.[3] Defendants do not cite any

3. *See Crossroads Systems (Texas), Inc. v. Dot Hill Systems Corp.*, 2006 WL 1544621 at *5 (W.D.Tex. May 31, 2006) ("the overwhelming weight of authority suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of evidence and arguments that may have been necessary to support the validity determination"); *Advanced Display Sys. v. Kent State Univ.*, 2002 WL 1489555 at *10 (N.D.Tex. July 10, 2002) (applying issue preclusion to earlier validity determination to prevent assertion

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countervailing authority, nor do they attempt to distinguish these cases.

Because it is undisputed that the validity of the '493 Patent was litigated in the *Syntex* action, the Court finds issue preclusion will prevent Defendants from relitigating the '493 Patent's validity unless an exception to the issue preclusion doctrine applies. The two arguments raised by Defendants regarding exceptions to issue preclusion are addressed below.

2. The Effect Of This Court's *In Limine* Ruling In Syntex Barring Obviousness Type Double Patenting And Best Mode Invalidity Arguments.

[15] Defendants assert that issue preclusion should not apply, at least to two of their invalidity arguments, because "there were at least two defenses (obviousness type double patenting and best mode) that Apotex was prepared to litigate in *Syntex* but the Court dismissed

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of even unasserted invalidity arguments); *Pall Corp. v. Fisher Scientific Co.*, 962 F.Supp. 210, 213 (D.Mass.1997) (finding that for purposes of issue preclusion, a litigant cannot raise different grounds to invalidate a patent in a second suit); *Zip Dee, Inc. v. Dometic Corp.*, 905 F.Supp. 535, 537 (N.D.Ill.1995) (applying issue preclusion to bar previously unasserted on-sale and public-use invalidity defenses). *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320 (Fed.Cir.2003), also cited by Plaintiffs, did not directly address the issue before this Court, and this Court does not rely on *Dana* in determining that issue preclusion applies here.

those defenses during pre-trial due to a technical defect." (Opp. at 18:7-9). Defendants presumably are referring to this Court's May 23, 2003 *in limine* order in *Syntex*, issued approximately ten days before trial, which barred Defendants from asserting obviousness type double patenting or best mode arguments because such theories were not disclosed until the eve of trial, prejudicing Plaintiffs.

To the extent Defendants are contending that the "issues" of obviousness type double patenting and best mode were not litigated in *Syntex*, this argument is unavailing in light of the reasoning set forth in *Applied*. Defendants litigated and lost the issue of invalidity before this Court in *Syntex*, and they are now barred from relitigating that issue, regardless of whether the specific arguments concerning invalidity were raised or not raised in *Syntex*.

To the extent Defendants are contending that they did not have a "full and fair opportunity" to litigate the issue of validity during the *Syntex* litigation because of the Court's *in limine* ruling, the Court finds that Defendants have made an inadequate showing. There is no doubt that "special circumstances—such as reason to doubt the quality, extensiveness, or fairness of procedures followed in prior litigation—may warrant an exception to the normal rules of preclusion. In short, the parties must have had a full and fair opportunity to litigate." *Durkin v. Shea & Gould*, 92 F.3d 1510, 1515 (9th Cir.1996) (citing *Montana v. United States*, 440 U.S. 147, 155, 164 n. 11, 99 S.Ct. 970, 59 L.Ed.2d 210 (1979)).

Here, however, Defendants make no showing that the procedures followed in the *Syntex* litigation that resulted in the exclusion of obviousness type double patenting and best mode arguments—namely, enforcement of the pleading and notice requirements of the Federal Rules of Civil Procedure and this district's Patent Local Rules—were unfair to Defendants. To the contrary, this Court's decision to exclude these specific invalidity arguments from the bench trial in *Syntex* was itself based on considerations of fairness. Moreover, Defendants had an opportunity to challenge these procedural rulings as part of their direct appeal to the Federal Circuit in the *Syntex* matter.

Accordingly, this Court finds that this Court's *in limine* rulings provide no basis to depart from the ordinary rules governing issue preclusion.

3. The Effect Of The Supreme Court's *KSR* Decision Regarding The Obviousness Standard.

Defendants also contend, with respect to their invalidity attack premised on obviousness, that the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex, Inc.*, __ U.S. __, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007) constitutes a change in law necessitating an exception to issue preclusion here. Plaintiffs respond that *KSR* does not constitute a sufficient change in law to trigger this exception to the issue preclusion doctrine.

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Issue preclusion will apply to prevent relitigation of previously determined issues "unless there have been major changes in the law." *Montana v. United States*, 440 U.S. 147, 161, 99 S.Ct. 970, 59 L.Ed.2d 210 (1979). Legal conclusions may be reexamined only if there has been "a significant change in the legal climate." *Kamilche*, 53 F.3d at 1063 n. 3; *see also Steen v. John Hancock Mut. Life Ins. Co.*, 106 F.3d 904, 914 (9th Cir.1997).

The question of whether *KSR* constitutes a major change in the law of obviousness sufficient to preclude application of issue preclusion appears to this Court to be an issue of first impression. In *KSR*, the Supreme Court identified several problems with the "teaching, suggestion, or motivation" ("TSM") test as applied by the Federal Circuit, and found that the Federal Circuit's rigid application of the test in the case before it was inconsistent with Supreme Court precedent. 127 S.Ct. at 1741-43. *KSR*'s actual holding was narrow, as it was limited to the Federal Circuit's application of the TSM test in the matter before it, and did not purport to overrule or overturn any other decisions. Nonetheless, subsequent lower court decisions have regarded *KSR* as a decision that may affect existing Federal Circuit precedent regarding application of the TSM test.[4] None

4. *See, e.g., Izzo Golf, Inc. v. King Par Golf, Inc.*, 2007 WL 1987789 at * 19 (W.D.N.Y. July 5, 2007) (permitting supplemental briefing because "KSR has substantively changed the law of obviousness"); *McNeil-PPC, Inc. v. Perrigo Company*, 2007 WL 1933931 at *15 (S.D.N.Y. July 3, 2007) ("KSR casts doubt on the (Cont'd)

of these decisions, however, expressly considered the question of whether *KSR* is a "major change in law" for purposes of issue preclusion.[5]

The Court need not resolve this question of first impression today. Even assuming, without deciding, that *KSR* constitutes a change in law sufficient to prevent application of issue preclusion to this Court's prior determination that the '493 Patent is non-obvious, Defendants are nonetheless precluded from relitigating the issue of obviousness under the claim preclusion doctrine, as discussed in more detail below.

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continuing validity of Federal Circuit precedent on the issue of obviousness"); *MercExchange, LLC v. eBay, Inc.*, 2007 WL 2172587 at *13 (E.D.Va. July 27, 2007) (*KSR* "plainly raised the bar as to what qualifies as non-obvious").

5. The Court disagrees with Plaintiffs that the Federal Circuit has already found *KSR* not to constitute a significant change in law in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed.Cir. June 28, 2007). *Takeda* did not involve a question of issue preclusion, and the Federal Circuit did not address the question relevant to this Court's inquiry—whether *KSR* constituted a significant change in law from earlier Federal Circuit precedent. Rather, *Takeda* merely applied the standards articulated in *KSR* to its direct review of the district court's findings, found that certain Federal Circuit standards for prima facie obviousness attacks upon chemical compounds remained consistent with *KSR*, and ultimately concluded the district court had not erred in holding that the accused infringer failed to establish a prima facie case of obviousness. *See id.* at 1356-61.

Accordingly, the Court finds that issue preclusion bars Defendants from asserting unenforceability of the '493 Patent, and bars Defendants from asserting all invalidity theories other than obviousness. Because (as discussed below) claim preclusion bars Defendants' efforts to relitigate the question of obviousness, the Court does not decide the question of whether issue preclusion also bars this particular invalidity theory.

C. Claim Preclusion Bars Defendants From Asserting Unenforceability or Invalidity In This Litigation.

Plaintiffs contend that, as a result of the *Syntex* litigation, claim preclusion bars Defendants from asserting that the '493 Patent is unenforceable or invalid.

1. The Elements Of Claim Preclusion Are Satisfied.

Under the doctrine of claim preclusion, "[a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." *Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 398, 101 S.Ct. 2424, 69 L.Ed.2d 103 (1981). Claim preclusion applies when "the earlier suit (1) involved the same 'claim' or cause of action as the later suit, (2) reached a final judgment on the merits, and (3) involved identical parties or privies." *Mpoyo v. Litton Electro-Optical Systems*, 430 F.3d 985, 987 (9th Cir.2005) (quotations omitted).

The second and third requirements of this test are met. It is not disputed that the parties here were also parties to the *Syntex* litigation. Moreover, the Syntex litigation reached a final judgment on the merits, in which this Court decided that the '493 patent is enforceable and not invalid. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants contend that the resolution in *Syntex* is not yet a "final judgment on the merits" because they have filed a still-pending petition for a writ of certiorari before the United States Supreme Court. This argument is contrary to law. The preclusive effect of a federal district court judgment is unaffected by any appeals pending therefrom. *See, e.g., Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir.1988).

The applicability of claim preclusion therefore turns on the first element—whether the *Syntex* lawsuit involved the same 'claim' or cause of action as this lawsuit. Defendants contend that the same claim is not at issue because the 0.4% KT ANDA formulation is materially different from the formulation at issue in *Syntex*. Plaintiffs contend that there is an identity of claims because any differences between the products are unrelated to the limitations of the claims of the '493 Patent.

For purposes of claim preclusion, the same "infringement claim" is raised by a second suit if the accused products in the two suits are "essentially the same." *Foster v. Hallco Manufacturing Co., Inc.*, 947

F.2d 469, 479-480 (Fed.Cir.1991) (applying Ninth Circuit law of claim preclusion). "Colorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent would not present a new cause of action" for purposes of claim preclusion. *Id.* at 480. A new claim is presented, however, if the newly accused products are "materially different" from those in the prior litigation. *See id.*[6]

Here, the undisputed record indicates that the accused products in the *Syntex* litigation and in this litigation are essentially the same. The only colorable changes identified by Defendants are "unrelated to the limitations in the claim of the patent", and therefore cannot prevent the application of claim preclusion. The formulations in the *Syntex* litigation and in this litigation contain the same identical ingredients. While the concentrations of four ingredients in the ANDA 77-308 formulation differs slightly from the formulation involved in *Syntex*, all fall well within the ranges for these ingredients claimed by the '493 Patent. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16)). This evidence satisfies Plaintiffs' burden to demonstrate that the products are "essentially the same."

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6. Defendants' contentions that the '493 Patent is invalid and unenforceable are not "claims" for purposes of claim preclusion. Instead, such assertions are treated as defenses to the patent owner's infringement claim. *See Foster,* 947 F.3d at 478-79.

In an effort to nonetheless establish a material difference between the accused products in the two lawsuits, Defendants rely solely on the declaration of their expert, Dr. Mitra. Dr. Mitra's declaration contains analysis and descriptions of experiments indicating that Octoxynol 40 is able to form micelles in the 0.5% KT ANDA formulation but not in the 0.4% KT ANDA formulation. (Mitra Decl., ¶¶ 42, 51.) Even if accepted as admissible testimony, however, this evidence does not establish a material difference in the two formulations.[7] The claims of the '493 Patent have no limitations relating to the stability of the formulation or to the formulation of micelles. Because the ability of Octoxynol 40 to form micelles is unrelated to the limitations of the claim of the patent, it cannot differentiate the accused formulations for purposes of claim preclusion. *See Foster*, 947 F.2d at 480; *see also Hallco Mfg. Co., Inc. v. Foster*, 256 F.3d 1290, 1295-98 (Fed.Cir.2001).

2. No "Change Of Law" Or Fairness Exception Prevents Claim Preclusion Here.

Alternatively, pointing to the Supreme Court's decision in *KSR*, Defendants contend that even if the elements of claim preclusion are satisfied, principles of fairness dictate that claim preclusion should not apply when there has been a change in the law. This contention is contrary to governing law and miscomprehends *res judicata* principles.

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7. Because Dr. Mitra's testimony would not suffice to establish a material difference in the formulations, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra.

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Under controlling precedent from the Supreme Court and the Ninth Circuit,[8] the fact that a judgment may have been wrong, or have rested on a since-repudiated legal principle, does not alter the claim preclusive effect of a final judgment. *See Federated Dept. Stores, Inc. v. Moitie,* 452 U.S. 394, 398, 101 S.Ct. 2424, 69 L.Ed.2d 103 (1981) ("Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case."), *Chicot County Drainage Dist. v. Baxter State Bank,* 308 U.S. 371, 374-75, 60 S.Ct. 317, 84 L.Ed. 329 (1940) (claim preclusion applied even though statute upon which prior case was decided was subsequently declared unconstitutional); *Clifton v. Atty. Gen. Of State of Cal.,* 997 F.2d 660, 663 (9th Cir.1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); *Government of Guam v. Cruz,* 869 F.2d 1326, 1327 (9th Cir.1989) (claim preclusion prevents relitigation of dispute "even if the court in the first litigation was wrong in its determinations").[9]

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8. For purposes of analyzing the claim preclusive effect of judgments in patent cases, the law of the regional circuit, not of the Federal Circuit, controls. *See Hartley v. Mentor Corp.,* 869 F.2d 1469, 1471 n. 1 (Fed.Cir.1989); *Foster,* 947 F.2d at 477 n. 7.

9. *See also* 18 Moore's Federal Practice § 131.12[3] (Matthew Bender 3d ed.) ("The doctrine of claim preclusion is

(Cont'd)

Appendix C

Defendants cite to no authority supporting their position that principles of fairness create an exception to ordinary claim preclusion principles where a change in law has occurred.[10] To the contrary, the Supreme Court has counseled courts against case-by-case evaluation of the equities when applying claim preclusion principles:

> The doctrine of res judicata serves vital public interests beyond any individual judge's ad hoc determination of the equities in a particular case. There is simply no principle of law or equity which sanctions the rejection by a federal court of the salutary principle of res judicata.... [T]he mischief which would follow the establishment of precedent for so disregarding this salutary doctrine against prolonging strife would be greater than the benefit which would result from relieving some case of individual hardship.

(Cont'd)
not concerned with whether a prior judgment was right or wrong or whether subsequent changes in the law, the discovery of additional facts, or considerations of fairness should merit a different result in the subsequent litigation").

10. Defendants did not address, in their opposition, the Supreme Court or Ninth Circuit authority cited by Plaintiffs. Instead, Defendants attempted to distinguish, largely unsuccessfully, certain out-of-circuit decisions that recognize the same principle that a change in law will not prevent application of claim preclusion.

Federated Dept. Stores, 452 U.S. at 401-02, 101 S.Ct. 2424.

Accordingly, the Court finds that claim preclusion applies here to bar Defendants' contentions that the '493 Patent is invalid and unenforceable, including Defendants' contention that the '493 Patent is invalid for obviousness.

D. Scope Of Order Authorized By 35 U.S.C. § 271(e)(4).

35 U.S.C. § 271(e)(4) provides, in relevant part, that for acts of infringement described in Section 271(e)(2):

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

The parties dispute the appropriate scope of an order under this statutory provision. Plaintiffs cite to 21 U.S.C. § 355a(a)(2) (B), a statutory mandate directed to the FDA, in support of their contention that the Court should issue an order requiring that the effective date of any approval of ANDA 77-308 be not earlier than the date six months after the expiration of the '493 patent.[11] Defendants contend that such an order would

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11. 21 U.S.C. § 355a(a)(2)(B) provides that where the FDA has granted pediatric exclusivity to the listed drug, as the FDA has done for ACULAR® LS, "the period in which an [ANDA] may not be approved . . . shall be extended by a period of sixth months after the date the patent expires."

exceed the Court's authority by continuing to enforce an expired patent and by invading the province of the FDA, and that the Court should instead issue an order that simply tracks the language of 35 U.S.C. § 271(e)(4)(A).

The Court agrees with Defendants. 21 U.S.C. § 355a(a)(2)(B) does not provide a sufficient basis for this Court to restrict the FDA's approval of the ANDA beyond the expiration date of the patent. Accordingly, the Court will order, consistent with 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the drug be a date which is not earlier than the date of the expiration of the patent which has been infringed.

CONCLUSION

For the foregoing reasons, the Court finds that undisputed facts establish that Defendants' filing of ANDA 77-308 infringes claims 1-5, 15-16 of U.S. Patent No. 5,110,493, and **GRANTS** summary judgment in favor of Plaintiffs on Count One of Plaintiff's complaint on that basis. The Court further finds, applying claim and issue preclusion principles as described above, that Defendants may not relitigate this Court's prior judgment the '493 Patent is enforceable and not invalid. Accordingly, the Court **GRANTS** summary judgment in favor of Plaintiffs on Defendants' counterclaim and defenses relating to invalidity and unenforceability.

Appendix C

Pursuant to 35 U.S.C. § 271(e)(2)(A), the Court further **ORDERS** that the effective date of any approval of ANDA 77-308 be a date which is not earlier than the date of the expiration of the '493 Patent.

IT IS SO ORDERED.

Dated: September 11, 2007

s/ Martin J. Jenkins
MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DATED AND FILED SEPTEMBER 5, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on September 12, 2008.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 09/05/2008